PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
723351		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/AU2004/000873	30 June 2004	1 July 2003

International Patent Classification (IPC) or national classification and IPC

Int. Cl.[7] A61K 38/18, A61P 9/10, 13/12, 17/02, AO1K 67/027

Applicant

BAKER MEDICAL RESEARCH INSTITUTE et al

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:

a. ☐ *(sent to the applicant and to the International Bureau)* a total of sheets, as follows:

☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of the report
12 January 2005	27 May 2005
Name and mailing address of the IPEA/AU	Authorized Officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	**M. Ong** Telephone No. (02) 6283 2491

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/000873

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1 (b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

☒ the international application as originally filed/furnished

☐ the description:

pages	as originally filed/furnished	
pages*	received by this Authority on	with the letter of
pages*	received by this Authority on	with the letter of

☐ the claims:

pages	as originally filed/furnished	
pages*	as amended (together with any statement) under Article 19	
pages*	received by this Authority on	with the letter of
pages*	received by this Authority on	with the letter of

☐ the drawings:

pages	as originally filed/furnished	
pages*	received by this Authority on	with the letter of
pages*	received by this Authority on	with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/000873

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-32	YES
	Claims		NO
Inventive step (IS)	Claims	1-32	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-32	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The following document identified in the International Search Report have been considered for the purposes of this report:

D1: Ozbun, LL et al

Novelty (N): Claims 1-32

The present invention defines a method of modulating the level of an extracellular protein matrix (ECM) by modulating the expression or activity of cell division autoantigen (CDA), otherwise known as differentially expressed nucleolar TGF-beta 1 target (DENTT). In altering the levels of ECM, treatment or prevention of conditions related to an ECM protein is claimed. Further, the invention includes a method of screening for agents that achieves the desired results. The invention encompasses a method of diagnosing a condition related to synthesis of ECM protein in an animal through the determination of the level of CDA in a given sample.

D1 is directed to the identification of potential target gene cells involved in TGF-beta 1 mediated responses using a transforming growth factor-beta 1 responsive epithelial non-small-cell lung cancer cell line. It identified a 496 fragment, subsequently named differentially expressed nucleolar TGF-beta 1 target (DENTT). DENTT mRNA is induced by TGF-beta 1 and correlates with the induction of TGF-beta 1 mRNA, induction of extracellular matrix gene expression and inhibition of colony formation of TGF-beta 1. As none of the essential features of the claims are disclosed, claims 1-32 are considered to be novel.

Inventive Step (IS):Claims 1-32

D1 discloses that expression of DENTT or CDA is modulated by TGF-β1 in human lung cancer cells. It also discloses that extracellular matrix gene expression is induced with the induction of DENTT mRNA. However, TGF-β1 is also known to be involved in different biological pathways. The present invention is directed to the treatment or prevention of fibrotic disorders, for example systemic and local scleroderma, keloids, hypertrophic scars, artherosclerosis and restenosis through the alteration of ECM production. The claimed invention is therefore, considered to be not obvious in light of the cited document.

Industrial Applicability: Claims 1-32

Claims 1-32 have industrial applicability

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 26 and 27 relate to an agent or pharmaceutical composition that is capable of modulating ECM synthesis, identified through a screening step. These claims are not fully supported by the description as the agent or pharmaceutical composition is yet to be identified and could constitute well known substances that owe nothing to the present inventive concept.